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March 21, 2014

VIA ECF

Hon. Colleen McMahon
United States District Judge
United States District Court
500 Pearl Street, Room 1640
New York, New York 10007

Re: *United States ex rel. Kester v. Novartis Pharmaceuticals Corporation*, Civil Action No. 11-8196 (CM): Submission Pursuant to Fed. R. Civ. P. 9(b)

Dear Judge McMahon:

With the permission granted by your Honor at the March 14, 2014 scheduling conference, the undersigned respectfully submits this letter on behalf of Defendants Accredo Health Group, Inc. ("Accredo") and CuraScript, Inc. ("CuraScript") in the above-referenced matter. The letter describes the requirements for pleading a violation of the False Claims Act predicated on a relator's allegations of criminal conduct under the Anti-Kickback Statute.

As described in greater detail below, Relator Kester's claims against Accredo and CuraScript fail to set forth "'the who, what, when, where and how'" of their alleged fraud as required by Rule 9(b). *Kalin v. Xanboo, Inc.*, 526 F. Supp. 2d 392, 401 (S.D.N.Y. 2007) (citation omitted). Courts have repeatedly expressed "concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004) (citation and internal quotation marks omitted). Kester's allegations against Accredo and CuraScript fit that profile perfectly. The Second Amended Complaint ("Complaint" or "Compl.") (D.E. 93) does not identify a single specific employee of either company, let alone the date and place of a single fraudulent statement or act by either company. That is not surprising. Kester is a former Novartis employee who has never had any employment or similar relationship with either Accredo or CuraScript and is thus in no way a "whistleblower" as to these two defendants. Because the claims against Accredo and CuraScript are too vague to satisfy the pleading requirements of Rule 9(b), this Court should dismiss those claims.[1]

I. LIABILITY UNDER THE FALSE CLAIMS ACT

As relevant in this case, a person is liable under the False Claims Act (FCA) if he or she "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or

[1] Because this submission is limited to Rule 9(b), Accredo and Curascript reserve their ability to pursue additional arguments in a motion to dismiss filed by April 21. D.E. 142.

approval," "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or "conspires to commit a violation" of either of those provisions. 31 U. S. C. § 3729(a)(1)(A-C). To state a claim under the FCA, Relator must allege that the defendants: "(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001). The first element is often the most critical, "because liability under the Act attaches only to a claim actually presented for payment, not to the underlying fraudulent scheme." *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013), *petition for cert. filed*, 81 U.S.L.W. 3650 (May 10, 2013) (No. 12-1349).

II. RULE 9(B) REQUIRES RELATOR TO IDENTIFY SPECIFIC CLAIMS SUBMITTED FOR PAYMENT

Because "the FCA is an anti-fraud statute …., claims brought under the FCA fall within the express scope of Rule 9(b)." *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam). Relator must therefore: "'(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 747 (2d Cir. 2009) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)).

Moreover, because of the False Claims Act's focus on specific claims for payment rather than fraudulent schemes more generally, "[c]ourts in the Second Circuit have held that 'allegations of violations of federal regulations are insufficient to establish a claim under the FCA if plaintiff cannot identify, with any particularity, the actual false claims submitted by the defendant.'" *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, No. 10 Civ. 7504(RA), -- F. Supp. 2d --, 2013 WL 4441509, at *16 (S.D.N.Y. Aug. 16, 2013) (citation omitted); *see also United States ex rel. Moore v. GlaxoSmithKline, LLC*, No. 06 Civ. 6047(BMC), 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (complaint must allege "with particularity" the "actual false claims submitted to the government"); *United States v. Wells Fargo Bank, N.A.*, 12 CIV. 7527 JMF, -- F. Supp. 2d --, 2013 WL 5312564, at *17 (S.D.N.Y. Sept. 24, 2013) (complaint must "'provide [] examples of specific false claims submitted to the government pursuant to'" the alleged fraudulent scheme (citation omitted)).

A few courts *outside* of this Circuit have relaxed Rule 9(b)'s requirements slightly, allowing an FCA complaint to proceed without identification of specific claims for payment in circumstances where the plaintiff identifies "probable, nigh likely, circumstantial evidence that" the ordinary billing system would "in due course … present fraudulent claims to the Government." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009). The majority of Circuit Courts to have addressed the question, however, have been unwilling to relax Rule 9(b)'s specificity requirement. *See, e.g., United States ex rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1313 (11th Cir. 2002) (district court "properly dismissed [Relator's] first Amended Complaint because he failed to identify a single claim that was actually submitted pursuant to the allegedly fraudulent schemes identified" (citation and internal quotation marks omitted)); *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of*

Utah, 472 F.3d 702, 727 (10th Cir. 2006) (To "meet the particularity requirements of Rule 9(b)," an FCA complaint must include "'allegations, stated with particularity, of the actual false claims submitted to the government.'" (citation omitted)); *Nathan*, 707 F.3d at 457 ("[A] relator must allege with particularity that specific false claims actually were presented to the government for payment."); *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("We hold that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 559-60 (8th Cir. 2006) (requiring "representative examples" of false claims). And, in line with that majority rule, "the weight of authority from district courts within this Circuit is that where an alleged FCA violation involves the submission of a false claim to the Government for reimbursement, the details of that false claim must be pled with particularity." *Moore*, 2013 WL 6085125, at *3.

Without even acknowledging this majority rule, the Government's letter responding to Novartis's motion to dismiss identifies a single unpublished decision in this District that is—it says—in "*accord*" with the minority position adopted by the Fifth Circuit. *See* D.E. 163 at 4 (citing *United States v. Huron Consulting Grp., Inc.*, No. 09 Civ. 1800(JSR), 2011 WL 253259, at *2 (S.D.N.Y Jan. 24, 2011). But while *Huron* adopted parts of the reasoning from *Grubbs* on general pleading standards in FCA cases, it also indicated that "'a relator must provide details that identify particular false claims for payment that were submitted to the government.'" *Id.* at *2 n.2 (quoting *Karvelas*, 360 F.3d at 232-33). The Government's reliance on *Huron* is thus misplaced.

Under the majority approach followed by courts within this Circuit, none of Relator's claims against Accredo or CuraScript meets the requirements of Rule 9(b). The Complaint does not identify even a single claim for payment submitted by either pharmacy. "Dismissal is appropriate on this basis." *Ping Chen*, -- F. Supp. 2d --, 2013 WL 4441509, at *17 (S.D.N.Y. Aug. 16, 2013); *see id.* at *17, 22 (noting that "[n]owhere in the Complaint … does Plaintiff identify a particular false claim that was submitted to the government for payment by any Defendant" and therefore dismissing claims under § 3729(a)(1)(A-C)).

The most specific of the paragraphs in the Complaint, paragraph 130, purports to identify a handful of *prescriptions* for a single drug (Exjade), and alleges generically that those prescriptions were "paid for" by Medicare Part D and Medicaid programs in Nevada, New York, Georgia, and Texas (excluding one prescription allegedly filled by Bioscrip, all claims against whom have been dismissed). Even if identifying prescriptions rather than claims for payment were enough, however—and it is not—these allegations would not suffice.

First, the indicated prescriptions are irrelevant to the vast majority of the claims alleged in the Complaint. None of the alleged prescriptions was filled by CuraScript, which does not distribute Exjade. *See* Compl. ¶ 37. None of the prescriptions was for Gleevac, Tasigna, or TOBI, which—the Complaint alleges—were the subject of separate contracts and separate outreach efforts. *See id.* ¶ 95 (Gleevec and Tasigna); *id.* ¶ 100 (Exjade); *id.* ¶ 119 (TOBI). And none of the prescriptions was paid for by the Federal Employees Health Benefits Plan, U.S. Department of Defense TRICARE and CHAMPUS programs, or the Medicaid programs in the 23 other States mentioned in the Complaint.

Accordingly, even if the Relator had identified the specific claims for payment associated with the prescriptions, they would not support the claims against CuraScript, the claims involving drugs other than Exjade, or the claims involving benefit programs other than Medicare Part D and the four indicated state Medicaid programs. The specific claims identified must be "representative examples" of the targeted fraudulent scheme. *Joshi*, 441 F.3d at 557; *see also Wells Fargo Bank*, 2013 WL 5312564, at *16 (examples of specific false claims must be "sufficiently representative" to enable the defendant to 'infer with reasonable accuracy the precise claims at issue by examining the … representative samples'" (quoting *Bledsoe*, 501 F.3d at 511)). A claim can hardly be "representative" if it involves a different defendant, a different allegedly fraudulent contract, or a different reimbursement program or state. *See, e.g.*, *Apaace Commc's, Ltd. v. Burke*, 522 F. Supp. 2d 509, 517 (W.D.N.Y 2007) ("'Rule 9(b) does not allow a complaint to merely lump multiple defendants together but "require[s] plaintiffs to differentiate their allegations when suing more than one defendant ... and inform each defendant separately of the allegations surrounding his alleged participation in the fraud."'" (quoting *Swartz v. KPMG LLP*, 476 F.3d 756, 764-65 (9th Cir. 2007))).

Second, with respect to the remaining prescriptions, the Complaint fails to provide sufficient specificity to put Accredo on notice of the resulting claims for payment that the Relator alleges were false or fraudulent. It gives no invoice numbers, prices paid, quantities dispensed, or even dates—making it impossible, based on this information, for Accredo to determine whether claims for payment were ever submitted to the relevant government programs in connection with the listed prescriptions. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (1st Cir. 2009) (complaint must provide specifics such as "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, [and] the amount of money charged to the government" (citation and internal quotation marks omitted)). All Accredo can discern from the Complaint is that at some undetermined point after 2007, a few doctors prescribed Exjade to a few unnamed patients with conditions for which Exjade is prescribed, and the patients participated in Medicare or Medicaid. That is not the specificity that Rule 9(b) requires.

Even under the more relaxed standard adopted by some courts *outside* this Circuit, the generalized allegations in Relator's Complaint—which focus on Novartis's intentions rather than the concrete actions of Accredo and CuraScript—fail to identify circumstantial evidence making it "more than probable" that Accredo and CuraScript presented false claims for payment. *Grubbs*, 565 F.3d at 192. Under that standard, too, Kester's Complaint would therefore fail.

III. WHERE FCA VIOLATIONS ARE PREMISED ON ANTI-KICKBACK STATUTE VIOLATIONS, RELATOR MUST PLEAD WITH SPECIFICITY ALL THE ELEMENTS OF AN ANTI-KICKBACK STATUTE VIOLATION

Where, as here, Relator seeks to meet the "falsity" element of the FCA by showing that the defendant falsely certified compliance with the Anti-Kickback Statute, 42 U. S. C. § 1320a-7b(b), or that an underlying Anti-Kickback violation rendered the claims otherwise "false," he must plead the elements of the Anti-Kickback Statute with specificity. *See, e.g.*, *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 (FB)(VVP), 2013 WL 1346022, at *5 (E.D.N.Y. Apr. 3, 2013) ("Plaintiff has thus failed to plead the fraudulent referral scheme with

the requisite particularity."); *United States ex rel. Antoon v. Cleveland Clinic Found.*, No. 3:12-cv-027, -- F. Supp. 2d. --, 2013 WL 5657597, at *13 (S.D. Ohio Oct. 16, 2013) ("[V]iolation of the Anti-Kickback Statute is not pled with the required plausibility."). That is because the "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b)." *Karvelas*, 360 F.3d at 232.

The Anti-Kickback Statute is a criminal statute that requires, as relevant here, a showing that the defendant (1) "knowingly and willfully" (2) solicited or received (3) remuneration (4) "in return for" arranging for or recommending ordering a good (5) for which payment will be made under a Federal health care program. 42 U. S. C. § 1320a-7b(b)(1)(B).

The Complaint fails to plead these elements with the required specificity. First, the Complaint nowhere alleges that Accredo or CuraScript acted "willfully"—that is, "with the specific intent to do something the law forbids." *United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998) (construing § 1320a-7b(b)); *see also United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (same); *United States v. Bay State Ambulance & Hosp. Rental Serv. Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (same).[2] Because willfulness is a necessary element to an alleged Anti-Kickback Statute violation, and because the alleged violation of that statute is what Kester asserts renders the claims here false, Relator cannot simply plead in general terms that Accredo and CuraScript intended to violate the law. Their (unalleged) intent to do so is a key part of the "wrongful activities that result in the submission of fraudulent claims," and must therefore "be pled with particularity." *Karvelas*, 360 F.3d at 232. Relator, however, does not specifically allege any facts indicating that anyone at Accredo or CuraScript knew that the adherence programs were unlawful, or even wrongful, let alone who those individuals were.

Second, Relator's Complaint does not allege with particularity that the remuneration Accredo or CuraScript received under their contract was "in return for" the allegedly improper recommendations. The "in return for" element of the statute—which applies only to recipients of alleged kickbacks, not to payers—ensures that medical professionals who passively accept some benefit without agreeing to do (or actually doing) anything improper do not face criminal liability solely on the basis of the *payer*'s improper motives. *Compare* 42 U. S. C. § 1320a-7b(b)(1), *with id.* § 1320a-7b(b)(2). But unlike the Government's complaint, which at least attempts to allege "promises or commitments" Bioscrip made to Novartis, *see* Intervention Compl. ¶¶ 66, 217 (D.E. 62), Relator's Complaint alleges no specific promises or commitments

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[2] Prior to 2010, the Ninth Circuit had gone farther, requiring the Government to prove the defendant had knowledge that his conduct violated the Anti-Kickback Statute specifically. *See Hanlester Network v. Shalala*, 51 F.3d 1390, 1399-1400 (9th Cir. 1995). Congress overruled *Hanlester* in 2010 through the adoption of 42 U. S. C. § 1320a-7b(h), which provides that "actual knowledge of *this* section or specific intent to commit a violation of *this* section" is unnecessary, but Congress did not remove the "wilfully" requirement or otherwise undermine the majority rule under which a defendant had to have known that his or her conduct was unlawful.

Accredo and CuraScript offered in return for the rebate contracts, let alone who made them and when. Nor does it offer any statistics demonstrating a significant increase in refill rates at these specialty pharmacies after execution of the contracts, such as might indicate the existence of an illicit bargain.

IV. RELATOR MUST DEMONSTRATE THAT THE ALLEGED FALSE CLAIMS "RESULTED FROM" A VIOLATION OF THE ANTI-KICKBACK STATUTE

Finally, an FCA Relator who roots his case in a violation of the Anti-Kickback Statute must specifically allege the causal connection between the underlying violation and the alleged false claim. *See* 42 U. S. C. § 1320a-7b(g) (a claim that "includes items or services *resulting from* a violation of" the Anti-Kickback Statute "constitutes a false or fraudulent claim" (emphasis added)).

Here, too, Relator's Complaint falls short. To establish that claims for payment resulted from the fraudulent scheme, rather than from patients' ordinary need to fill their prescriptions, Relator would need to demonstrate that Novartis's rebate offers increased the refill rates at Accredo and CuraScript. The Complaint is bereft of any such allegations, either anecdotal or statistical. The few statistics the Complaint does offer go to irrelevant comparisons of sales figures and refill rates at retail versus specialty pharmacies. *See, e.g.*, Compl. ¶¶ 88, 118. The Complaint pleads no specific facts that would show that those differences result from the alleged kickback scheme, rather than from the pre-existing fundamental differences between specialty and retail pharmacies. For example, while paragraph 118 alleges that the percentage of TOBI sales made through specialty pharmacies increased over time, an earlier paragraph negates the significance of that fact by alleging a Novartis decision to increase its use of specialty pharmacies. *See id.* ¶113. What is entirely missing from the Complaint are any specific factual allegations of any change in the practices of Accredo or CuraScript after receiving the alleged kickbacks.

The Government attempts to avoid the causal connection required by the statute's "resulting from" language by citing the Third Circuit's decision in *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011). *See* D.E. 163 at 5-6. The single sentence the government quotes is followed—in the *Wilkins* decision, though not the Government's filing—by a footnote "emphasiz[ing] again that we are not reviewing these claims under the particularized pleading standards of Rule 9(b)." 659 F.3d at 313 n.20. Where, as here, Rule 9(b)'s standards apply, *Wilkins* is by its own account inapplicable.

V. CONCLUSION

For the foregoing reasons, the Court should dismiss Relator's FCA claims against Accredo and CuraScript. If it does so, the Court should also decline to exercise supplemental jurisdiction over the exclusively state-law claims that remain, *see* 28 U. S. C. § 1367(c)(3), which in any event are subject to the same Rule 9(b) objections as the FCA claims. *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704 (ERK), 2009 WL 1456582, at *4

(E.D.N.Y. May 22, 2009) ("Rule 9(b) applies to … *qui tam* actions under state statutes similar to the FCA.").

Respectfully yours,

/s/ Daniel Meron
of LATHAM & WATKINS LLP

cc: All Counsel of Record (via ECF)